

**Standard Operating Procedure for the
Review of Standards Submitted to the National Environmental Laboratory Accreditation
Conference (NELAC)**

**NELAC Standards Review Committee
Date: June 24, 2004
DRAFT - DO NOT QUOTE OR CITE**

Reviewed by NELAC Standards Review Committee: _____
Date

Reviewed by NELAC Board of Directors: _____
Date

Approved by NELAC: _____
Date

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Review of Standards Submitted to NELAC

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1. PURPOSE

The purpose of this standard operating procedure (SOP) is to ensure that all reviews of proposed standards submitted to the National Environmental Laboratory Accreditation Conference (NELAC) are carried out in a proper, timely, and consistent manner and in accordance with the NELAC Standard and the NELAC procedures and policies.

2. APPLICABILITY

This SOP applies to all standards submitted to the NELAC by Standard Development Organizations (SDOs).

3. SUMMARY

Standards review is the responsibility of the Standards Review Committee (SRC). The SRC will:

- a) review all standards received by NELAC from SDOs for consistency with governmental, regulatory, and NELAC requirements;
- b) prepare an assessment of the advantages and disadvantages of each standard;
- c) prepare and publish a report with recommendations for disposition of proposed standards received by the SRC;
- d) facilitate discussions of proposed standards at the NELAC interim meeting; and
- e) present proposed standards with recommendations to the NELAC membership for a vote at the NELAC annual meeting.

4. DEFINITIONS

Standards Review Committee (SRC) - a body of the NELAC comprised of one official from each National Environmental Laboratory Accreditation Program (NELAP) recognized accrediting authority (AA) and ten officials not from a NELAP-recognized accrediting authority (Article VI, Section 2, paragraph C of the NELAC bylaws).

Acceptable Standard Development Organization (ASDO) – See Section 1.5.1 of Chapter One (Program Policy and Structure) of the NELAC standard.

5. PROCEDURE

5.1 Reviews for Acceptability of the Standard Development Organization.

- a) Request or obtain the documents and/or materials necessary from the organization presenting standards to NELAC. These materials may include, but are not limited to, the organization's constitution and bylaws, policies, and procedures. Determine whether the proposed standard has been developed by an organization meeting NELAC's requirements as follows:
 - 1) Openness. Determine that the organization's process of developing standards is designed to be open. The organization ensures that standards are readily available, the organization allows any interested parties to review the standards, and provides a mechanism for submitting comments on those standards for consideration by the committee that develops the standard.

- 2) Balance of Interest. Determine that the organization has a process that defines how various segments (e.g., private vs. public or manufacturer vs. user) are distributed on committees to ensure a representative mixture of members so that a variety of interests are included. Indicate which document or material covers this condition for the organization.
 - 3) Due Process. Determine that the organization has a written policy that describes how a standard is adopted and the process for ensuring that a variety of opinions are considered in developing the standard; e.g., a ballot process that identifies the procedure for revising a standard and the basis for submitting and/or handling a negative vote on the standard would meet these criteria.
 - 4) Appeals Process. Determine that the organization has a defined consensus process that ensures general agreement, but not necessarily unanimity. It shall include a process for attempting to resolve objections by interested parties, including informing the objector of the disposition of his or her objection(s) and the reasons why, and a provision allowing committee members to change their votes after reviewing the objections.
 - 5) Document the documents and/or materials used to make the determination and indicate which documents and/or materials cover the conditions listed for an ASDO.
- b) If the proposed standard has not been developed by an acceptable SDO, the SRC chairperson will return it to the submitting party with a written explanation for the rejection.
- c) If the SRC determines that the proposed standard has been developed by an acceptable SDO, it will proceed with the completeness review.

5.2 Completeness Review of Proposed Standard.

Determine whether the proposed standard has been submitted in a format consistent with the NELAC Standards Style Manual. The proposed standard must be complete and must include all the information necessary for a review.

5.3 Technical Review of Standard.

- a) The SRC will form one or more subcommittees to review standards that the SRC has accepted. The subcommittee(s) will be comprised of members of the SRC and/or technical experts from outside the SRC membership as necessary to provide a comprehensive review. The subcommittee(s) will be appointed by the SRC Chair. The subcommittee(s) will include at least two members of the SRC preferably from NELAP recognized AAs.
- 1) The SRC will provide a written task assignment to each subcommittee.
 - 2) The subcommittee(s) will conduct a review of the proposed standard according to the task assignment and provide a written report of its findings and recommendations to the SRC. It will also present its findings at one of the SRC's subsequent teleconference.
- b) The SRC will prepare a summary of the technical review for presentation at the NELAC Interim Meeting. This summary must include the findings and recommendations of the subcommittee(s) and any additional explanation needed to enhance the proceedings during the open working session at the Interim Meeting. Make this summary available at least 30 days prior to the Interim Meeting. The summary will be available on the NELAC website.
- c) The SRC will hold an open working session at the NELAC Interim Meeting to consider all the proposed standards that have been submitted at least 90 days preceding that meeting.

- d) No later than 30 days after the Interim Meeting, the SRC will notify the SDO of the SRC's recommendations.
- e) The SRC will prepare a written assessment of the proposed standard that has been discussed at the Interim Meeting. Make available or reference (where the standard is available to the public) all proposed standards, together with the SRC's written assessment, at least 30 days prior to the Annual Meeting.
- f) For the SRC voting procedure, refer to Sections 5.1 through 5.8 of the "Standard Operating Procedure for the Voting Process of Acceptance of New Standards Submitted to NELAC." If, after the steps outlined in Section 5.8 of that SOP are taken, there is still an unresolved negative vote by an SRC member representing an accrediting authority, the SRC shall not recommend the proposed standard for adoption, but include (as an addendum, if necessary) a discussion of the proceedings surrounding the negative vote(s) in the report described in 5.3. e) of this SOP.
- g) The SRC will present the proposed standard with recommendations for voting at the NELAC annual meeting. These recommendations will be as follows:
 - 1) the standard will be recommended for NELAC approval without further modification;
 - 2) the standard will be recommended for NELAC approval subject to minor changes being made by the SDO; or
 - 3) the standard is considered unsuitable and will not be recommended for approval if brought to vote.
- h) If, during the voting session at the NELAC annual meeting, NELAC does not adopt a proposed standard, the SRC will prepare a report of the reasons to the extent known and return it to the SDO within 30 days of that annual meeting.

6. QUALITY CONTROL

The NELAC Board of Directors and the NELAP Director will assess the performance of the SRC review process annually.

7. REFERENCES

NELAC Chapter One, Revision 16, June 5, 2003.